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Surgery for women with pelvic organ prolapse

Submission date
16/03/2009

Recruitment status
No longer recruiting

Registration date
13/05/2009

Overall study status
Completed

Last Edited
18/12/2019

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pelvic organ prolapse is bulging of one or more of the pelvic organs into the vagina. Surgery to treat pelvic organ prolapse is relatively common. Around 1 in 10 women will need prolapse surgery at some point in their lives. There is not enough evidence from research to identify which operation is best. New techniques have been introduced which use mesh to reinforce the surgery, but these have not been properly tested, especially in terms of how well they improve prolapse symptoms. In particular, there is not enough information on the effectiveness and safety of the mesh used in prolapse surgery in women.

Who can participate?
Women having a prolapse operation

What does the study involve?
Women who are having their first repair operation are randomly allocated to undergo either a standard prolapse repair, or a standard repair with a biological graft to support the stitches, or a standard repair with a mesh to support the stitches. Women who are having their second or subsequent repair are randomly allocated to undergo either a standard prolapse repair, or a standard repair with a mesh to support the stitches, or a new mesh repair using an introducer (mesh kit). This last option is only available for women having a secondary operation for prolapse as it is thought that it is more invasive than the other options, and so should be reserved for such women because they have a higher risk of failure. Women who do not wish to be randomly allocated, but are happy for their outcomes to be monitored, are examined and complete the questionnaires in the same way as the other groups. Women have a routine gynaecological examination before surgery and they complete questionnaires both before and after their operation. Further symptom questionnaires are also filled in 6, 12 and 24 months later. The women are examined and reviewed in outpatients at 4 to 6 months after surgery.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?
June 2009 to May 2014

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 07/60/18

Study information

Scientific Title
Clinical and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse: two randomised controlled trials within a comprehensive cohort study

Acronym
PROSPECT

Study objectives
Which prolapse operations are the safest and most effective and cost-effective for women with pelvic organ prolapse?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/076018
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/51897/PRO-07-60-18.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study will be submitted to the North of Scotland Research Ethics Committee in April 2009 - pending

Study design
Multi-centre randomised controlled trial and comprehensive cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vaginal wall prolapse

Interventions
All women having primary or secondary pelvic organ prolapse surgery for anterior and/or posterior vaginal wall prolapse and who consent to participate will be included in the study.

If the treating gynaecologist advises that any of the repair procedures are suitable for the patient and the woman agrees to randomisation), she will be randomised into the following arms:

For women having a primary repair:
Arm 1: Standard anterior and/or posterior repair (central plication) (reference technique)
Arm 2: Standard anterior and/or posterior repair with biological mesh inlay
Arm 3: Standard anterior and/or posterior repair with a non-absorbable or hybrid mesh inlay

In women having a secondary repair the three arms are:
Arm 1: Standard anterior and/or posterior repair (central plication) (reference technique)
Arm 2: Standard anterior and/or posterior repair with a non-absorbable or hybrid mesh inlay
Arm 3: A mesh kit (using an introducer device) with a non-absorbable or hybrid mesh

The patients who are not eligible for randomisation (if the gynaecologist advises one particular repair and/or the woman is not willing to be randomised) will be invited to consent to join the comprehensive cohort study.

All women, whether in the randomised controlled trials or the comprehensive cohort, will be followed-up in the Gynaecology Outpatients Department at around 3 to 6 months after surgery. Questionnaires will be posted to all participants at 6, 12 and 24 months after randomisation.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Primary patient-reported outcome:
1.1. Symptoms of prolapse, measured as the frequency of prolapse symptoms on the Pelvic Organ Prolapse Symptom Scale (POP-SS) at two years after surgery
1.2. Quality of life (Visual Analogue Scale) outcome measured as the overall effect of prolapse symptoms on everyday life
2. Cost effectiveness: incremental cost per quality-adjusted life year (QALY) based on Euroqol EQ-5D data

All primary and secondary outcomes are measured at 6, 12 and 24 months, measured in participant-completed questionnaires.

Key secondary outcome(s))

1. General
1.1. Immediate and late post-operative morbidity
1.2. Other adverse effects or complications including mesh erosion or removal
1.3. Operating time
1.4. Blood loss
1.5. Number of nights in hospital
1.6. Time until resumption of usual activities
1.7. Need for further surgery for prolapse or for urinary incontinence
1.8. Time to further surgery
1.9. Satisfaction with surgery

2. Prolapse outcomes
2.1. Subjective recurrence of prolapse
2.2. Subjective continuation /recurrence of prolapse symptoms
2.3. Objective residual prolapse stage (POP-Q) at original site
2.4. Development of new (de novo) prolapse at another site
2.5. Need for other conservative prolapse treatment (e.g., pelvic floor muscle training [PFMT], mechanical device)

3. Urinary outcomes
3.1. Urinary incontinence (persistent or de novo, and types of incontinence)
3.2. Need for alternative management for incontinence (e.g., PFMT, mechanical devices, surgery, drugs, intermittent catheterisation)

4. Bowel outcomes
4.1. Constipation (persistent or de novo)
4.2. Faecal incontinence (persistent or de novo)

5. Sexual function outcomes
5.1. Dyspareunia/ apareunia/ difficulty with intercourse
5.2. Vaginal symptoms

6. Quality of life outcome measures
6.1. Condition-specific quality of life measure (e.g. physical activity, social, hygiene, sexual)
6.2. General health measures

7. Economic outcome measures
7.1. Cost and use of NHS services
7.2. Cost to the women and their families/carers
7.3. QALYs estimated from the responses to Euroqol EQ-5D
7.4. Incremental cost per QALY (QALYs based on the SF-12® Health Survey data)
7.5. The incremental costs, QALYs and incremental cost per QALY derived by the economic model

All primary and secondary outcomes are measured at 6, 12 and 24 months, measured in participant-completed questionnaires.

Completion date
30/04/2020

Eligibility

Key inclusion criteria
Women (no age limits) having primary or secondary pelvic organ prolapse surgery for anterior and/or posterior vaginal wall prolapse who are willing and eligible to be randomised

Notes:
1. Women who are unwilling or ineligible for randomisation will be eligible to be followed up using the same protocol as part of the comprehensive cohort
2. Women undergoing concurrent hysterectomy/cervical amputation, vault surgery or continence procedures are also eligible

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Women undergoing prolapse surgery who are unwilling or unable to participate in the study
2. Women who are unable or unwilling to give competent informed consent, or are unable to complete study questionnaires

Date of first enrolment
01/06/2009

Date of final enrolment
31/05/2014

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Aberdeen
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Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/01/2017		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes